

AMENDMENTS TO THE DRAWINGS:

The attached sheet of drawings includes changes to Figure 1. This sheet, which includes Figure 1, replaces the original sheet including Figure 1.

Attachment: Replacement Sheet

REMARKS

The application has been amended to place it into condition for allowance at the time of the next Official Action.

A replacement drawing is submitted for Figure 1 adding labels for the blocks consistent with the specification. The above change is the only change and is believed not to introduce new matter, while addressing the drawing objection entered on page 2 of the Official Action.

The specification is amended to make editorial changes therein, including addressing the specification objection entered at the bottom of page 2 of the Official Action. Please note that the term "pulsimeter" has been changed throughout the specification to read "pulse strength meter", which more accurately reflects the device that measures the strength of the patients pulse. The above change is believed not to introduce new matter.

Claims 16-37 were previously pending in the application. Claims 16-37 are canceled and replaced with new claims 38-63.

Claim 45 includes the suggestions in the Official Action to address the claim objection as to that claim.

Claims 46 and 49 clarify that the pulse strength meter measures the pulse strength.

The recited "coupling medium" in claim 50 is believed to have proper antecedent basis in line six of claim 38 from which claim 50 depends.

Claim 57 provides further steps to further limit claim 55.

Claim 58 provides further steps to further define the method.

The above changes are believed sufficient to address the claim objections noted on page 3 of the Official Action.

Claims 40 and 55 provide proper antecedent basis for the recited elements.

Claim 52 recites structural features and claim 55 further defines the wave form with respect to frequency. A similar feature is in claim 56.

The above changes are believed sufficient to address the 35 U.S.C. 1.12 second paragraph rejections objections in the paragraph covering pages 3 and 4 of the Official Action.

Claims 16, 33 and 34 were rejected under 35 USC 102(e) as being anticipated by BRISKEN et al., U.S. 6,575,956. That rejection is respectfully traversed.

BRISKEN discloses an ultrasound delivery system operated within the frequency range of 20 kHz to 5 MHz (that is, it emits and delivers only ultrasonic waves into a tissue). Moreover, in every single ultrasound delivery cycle a continuous or a pulsed ultrasonic wave at a certain pre-set frequency is

emitted and delivered into said tissue portion for a given period of time, which means that the treatment within a single delivery cycle is performed with an ultrasonic wave of constant frequency, as is clear from the Examples discussed and, in particular, from the Tables provided.

Due to attenuation properties of ultrasonic waves in various kinds of biological tissues, according to which lower frequencies result in a greater penetration depths into the tissues provided that the energy density is kept unchanged, and vice versa, the applied ultrasonic waves cannot reach the deeply buried tissues during a treatment accomplished in harmony with the teaching of BRISKEN, unless the energy density is increased. However, the very high energy densities (i.e. about and above 60 W/cm²) required and applied at higher ultrasonic frequencies to reach an effective delivery might be damaging to the tissues due to their thermal effects and hence are not preferred.

Contrary to this, claims 38 and 54 are directed to an apparatus and a method of treatment respectively, wherein the ultrasonic waves are **applied in combination with infra- and audible sound waves** that are also emitted with the same treating head (or transducer) within the same delivery (or treatment) cycle, i.e. **the frequency** of the longitudinal waves (or sound waves) emitted and delivered into the tissue portion under treatment **is being continuously changed over time in one treatment cycle**.

In other words, the treatment of tissues according to the claimed invention takes place through longitudinal waves emitted at frequencies sweeping over the full range of 1 Hz to 100 kHz in pre-defined steps in one treatment cycle. Furthermore, said frequency steps are not equidistant over said frequency range, their lengths are changed over time.

By making use of the above combination of longitudinal waves, deeply buried tissue layers can also be reached and stimulated effectively, without the risk of being thermally damaged, as the treatment is effected with sound waves of relatively low energy density (i.e. at most 0.1 W/cm^2). When treatment is on, sound waves of different frequencies reach and are absorbed by different layers of the tissue treated. Therefore, when sweeping over the range of 1 Hz to 100 kHz, the tissue as a whole in its full depth is stimulated by means of sound waves having non-damaging energy densities.

By way of example, the attached illustration shows the positive effects of the treatment according to the invention on patients suffering from peripheral arterial stenosis. As is shown in the illustration, the walking distance in meter units plotted over the number of treatments performed by the combination of infra-, audible and ultrasound waves increase significantly in a very short time. This is also supported by the enclosed document entitled *Expert Opinion of Specialist in Vascular Surgery* by prof. L. Kollár, Dr. G. Menyhei and Dr. G. Kasza.

Such a solution, exploiting the above-discussed positive effects of the combined treatment with infra-, audible and ultrasonic waves is neither discussed nor even suggested by BRISKEN.

Accordingly, BRISKEN does not anticipate claims 38, 54 and 55.

Claims 17-21 were rejected under 35 USC 103(a) as being unpatentable over BRISKEN in view of GREY et al., U.S. 5,050,588. That rejection is respectfully traversed.

GREY does not overcome the shortcomings of BRISKEN set forth above with respect to claim 38. Rather, GREY discloses an ultrasonic transducer for emitting ultrasonic waves in a highly focused manner. As is clear from the above, an aim of the present invention is to expose tissue volumes as large as possible in a treatment cycle with longitudinal waves ranging from 1 Hz to 100 kHz, instead of delivering a focused ultrasonic wave into a tiny portion of said tissue volume. Therefore, GREY not only fails to overcome the shortcomings of BRISKEN, but also teaches away from the claimed invention.

Accordingly, it would not have been obvious to one of ordinary skill in the art to combine the references in the manner suggested to meet the present claims.

In view of the present amendment and the foregoing remarks, it is believed that the present application has been

placed in condition for allowance. Reconsideration and allowance are respectfully requested.

Please charge the fee of \$104.00 for the extra independent and dependent claims added herewith. The required filing fees are being paid online simultaneously herewith by credit card.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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APPENDIX:

The Appendix includes the following item(s):

- ☒ - an illustration
- ☒ - a Replacement Sheet for Figure 1 of the drawings
- ☒ - a Declaration of expert opinion